

REMARKS

I. Background

The present Amendment is in response to the Final Office Action mailed June 9, 2006. Claims 1-25 have been cancelled. New claims 26-35 have been added. As such, claims 26-35 are now pending for consideration.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

II. Proposed Claim Amendments

New claims 26-35 are of the same scope as claims originally filed and previously presented. The cancellation of claims 1-25 and presentation of new claims 26-35 has been made merely to simplify the pending subject matter to facilitate prosecution on the merits. As such, claims 26-35 are fully supported by the figures, chemical structures, specification, claims, and combinations thereof as originally filed. Specifically, the claims are supported as follows: claim 26 is supported by claim 1 as originally filed; claim 27 is supported by claim 2 as originally filed; claim 28 is supported by claim 3 as originally filed; claim 29 is supported by claim 4 as originally filed; claim 30 is supported by claim 8 as originally filed; claim 31 is supported by claim 9 as originally filed; claim 32 is fully supported by claim 10 as originally filed; claim 33 is fully supported by claim 14 as originally filed; claim 34 is supported by claim 15 as originally filed; and claim 35 is supported by claim 16 as originally filed. In view of the foregoing

discussion, Applicant submits that the amendments to the claims do not introduce new matter and entry thereof is respectfully requested.

III. Comments on Response to Amendments

Applicant respectfully disagrees with the Examiner's characterization of the amendments including new matter that is not supported in the specification. Applicant specifically pointed to the structures in Figure 10 that provided support for the proposed amendments; however, in view of the foregoing amendments Examiner's characterization is moot.

IV. Comments on Response to Amendments

The Examiner has alleged that the Office Action of February 7, 2006 provided a *prima facie* case of obviousness of claims 1-6 by listing the compound of *Keller* in view of the organic reaction of *McMurry*. The Examiner has alleged that because *McMurry* teaches a **basic type** of organic reaction, one of skill in the art would know that the carboxylic acid on the compound of *Keller* can be converted to a corresponding alcohol with reasonable chance to succeed. Additionally, the Examiner has alleged that the suggestion comes from *McMurry*. The Examiner further alleges that Applicant's assertion that the conversion reaction could only be made after reviewing the Applicant's disclosure and using hindsight is not persuasive. Moreover, the Examiner rejects claims 1-2 and 5-6 under § 112 for a lack of the written description requirement, and rejects claims 3-4, 10, and 16 under § 112 for lack of enablement.

Applicant respectfully objects to the Examiner's response to the Amendments and remarks. First, Applicant respectfully asserts that a compound could not be "obvious" and lack sufficient support in the specification. By the Examiner going to the art to search for a structure, such as in *Keller*, and going to the art to search for a conversion reaction, such as in *McMurry*, the Examiner has supported Applicant's contention that the synthesis of the claimed compounds is well within the skill of one of ordinary skill in the art. As such, by using the Applicant's specification, one of ordinary skill in the art could determine the synthesis for the claimed compounds. This is especially true when the entire specification, including Example 9, is considered in view of the skill of one of ordinary skill in the art. Example 9 was discussed in

Applicant's last remarks merely to show the simplicity of the synthesis of compounds, which are similar in structure and function with the claimed compounds.

Moreover, Applicant respectfully asserts that the specification need not be a technical treatise on chemical synthesis because "the law is clear that patent documents need not include subject matter that is known in the field of the invention and is in the prior art, for patents are written for persons experienced in the filed of the invention. . . . To hold otherwise would require every patent document to include a technical treatise for the unskilled reader." *S3 Inc. v. nVIDIA Corp.*, 259 F.3d 1364, 1371, 59 USPQ2d 1745, 1749-50 (Fed. Cir. 2001) citing *Vivid Technologies, Inc. v. American Science and Engineering, Inc.*, 200 F.3d 795, 804, 53 USPQ2d 1289, 1295 (Fed. Cir. 1999) ("Patents are written by and for skilled artisans"). Again, as evidenced by the Examiner using the Applicant's application as a roadmap to find both *Keller* and *McMurry*, the synthesis of the claimed compounds is well within the skill of one of ordinary skill in the art with the Applicant's application in hand.

V. Rejection on the Merits

A. Rejections Under 35 U.S.C. § 103

The Examiner rejects claims 1-6 under 35 U.S.C. § 103 as being unpatentable over *Keller et al. Helvetica Chimica Acta* (1975), 58(2), 531-41 (hereinafter "*Keller*") in view of Organic Chemistry by *McMurry* 2nd edition on page 727, section 20.8, reduction of carboxylic acids to alcohol by LiAlH_4 (hereinafter "*McMurry*"). The Applicant respectfully traverses the rejection because the Office Action has not established a *prima facie* case of obviousness.

According to the applicable law, a claimed invention is unpatentable for obviousness if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (2005); *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966); MPEP 2142. Obviousness is a legal question based on underlying factual determinations including: (1) the scope and content of the prior art, including what that prior art teaches explicitly and inherently; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18; *In re Dembiczak*, 175 F.3d 994, 998 (Fed. Cir. 1999). It is the initial burden of the PTO to

demonstrate a *prima facie* case of obviousness, which requires the PTO to show that the relied upon references teach or suggest all of the limitations of the claims. MPEP 2142 (emphasis added).

According to MPEP section 2143:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)."

(Emphasis added).

As indicated by the Examiner, *Keller* teaches a chemical compound that has the formula shown on page 5 of the Office Action of Feb. 7, 2006. Additionally, *Keller* teaches the maleoyl group of the compound can be cleaved by mild alkaline and acid hydrolysis. However, *Keller* does not teach or suggest a relevant method of synthesis of the chemical compound, a relevant method of a conversion synthesis, or a relevant use of the chemical compound. Moreover, *Keller* does not teach or suggest any method of reacting the carboxyl group into a different functional group, or provide any suggestion or motivation for reacting the carboxyl group.

As indicated by the Examiner, *McMurry* teaches a method of converting -COOH to CH₂OH (hereinafter "conversion reaction"). More particularly, *McMurry* only shows the conversion reaction with aliphatic compounds that only have the -COOH as the sole functional group for reaction. That is, *McMurry* only teaches the conversion reaction with aliphatic compounds having only the -COOH group being capable of a reduction reaction with a powerful hydride reagent, such as lithium aluminum hydride to yield a primary alcohol. Also, *McMurry* states that the reaction is difficult and often requires heating in tetrahydrofuran solvent to go to completion.

On the other hand, *McMurry* is completely devoid of teaching or suggesting the conversion reaction for compounds has more than one functional group. Further, *McMurry* is completely devoid of teaching or suggesting that a maleimide compound having a carboxylic acid could be converted by the conversion reaction to a maleimide compound having a primary

alcohol. In fact, nothing in *McMurry* suggests the consequence of having a maleimide functional group in the presence of a powerful hydride, such as lithium aluminum hydride. Moreover, nothing in *McMurry* suggests the consequences of the conditions on the maleimide functional group that are required to facilitate the conversion reaction (e.g., heat, tetrahydrofuran, and lithium aluminum hydride). Thus, *McMurry* does not teach or suggest that the chemical of *Keller* can be modified by the conversion reaction to successfully arrive at the presently claimed invention.

1. Hindsight

In response to the combination of *Keller* and *McMurry*, Applicant reasserts that hindsight has been used to make the combination of references. This is because the material in an application will often seem obvious in light of the prior art once the Applicant's disclosure is known. The opportunity to judge an application by hindsight is particularly tempting. Consequently, the tests of whether to combine references need to be applied rigorously. See *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999), limited on other grounds by *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (2000) (guarding against falling victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher).

Accordingly, Applicant respectfully asserts that Examiner's combination of a reference (i.e., *Keller*) that teaches a specific chemical compound with a reference (i.e., *McMurry*) teaching a specific conversion reaction could only be made after reviewing the Applicant's disclosure and using hindsight. In fact, neither *Keller* nor *McMurry* teaches the claimed class of chemical compounds, and further neither teaches a method of synthesizing the same. Thus, Applicant's application for patent had to be used to determine the specific reagent of *Keller* and the specific conversion reaction of *McMurry* because, absent the Applicant's application for patent, the product of the conversion reaction is not taught or suggested.

Additionally, Applicant respectfully asserts that the generic teaching in *McMurry* of the conversion reaction for aliphatics having a sole functional group (i.e., carboxylic acid) as the suggestion for being combined with *Keller* can only be based in hindsight. In part, this is because if such teaching provided the motivation, then it would be obvious to modify every single molecule having a carboxylic acid into a molecule having a primary alcohol. In fact, such

a concept is akin to a "needle in the haystack" where after having the conversion reaction the prior art is sifted to find a molecule that can undergo the conversion reaction to arrive at the presently claimed invention. It is well established that one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). By asserting that *McMurry* provided the motivation, hindsight was necessarily used to reconstruct the present invention because nothing in *McMurry* provides any teaching or suggestion for using the conversion reaction for any of the following: a conversion reaction of a molecule having a carboxylic acid and another functional group; a conversion reaction of a molecule having a carboxylic acid and a malcimide; or a conversion reaction with a molecule having a malcimide; or a conversion reaction to modify any compound to arrive at the claimed invention.

In view of the foregoing, Applicant respectfully requests the rejection be withdrawn due to the Examiner's use of hindsight to reconstruct the Applicant's claimed invention.

2. No Suggestion or Motivation for Combination

Applicant respectfully asserts that there is no suggestion or motivation arising from *Keller* and *McMurry*, alone or in combination, to make such a combination of references. It is known that just because different elements of an invention may be found in different references does not allow for a combination of such references to reconstruct the Applicant's invention. Accordingly, the Court has stated that "[t]he genius of invention is often a combination of known elements which in hindsight seems preordained. To prevent hindsight invalidation of patent claims, the law requires some "teaching, suggestion or reason" to combine cited references. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ2d 1378, 1383 (Fed. Cir. 1997). Correspondingly, disclosure of a specific chemical compound or a specific conversion reaction does not alone provide any motivation or suggestion to combine such a chemical compound with a conversion reaction, or *visa versa*, to convert the chemical compound into a specific analog.

As stated above, *Keller* only teaches a specific chemical compound. Nothing in *Keller* teaches or suggests any modifications, substitutions, or derivations of the chemical compound to obtain the Applicant's claimed chemical compound. In fact, *Keller* teaches that the malcoyl group of the compound can be cleaved by mild alkaline and acid hydrolysis. Additionally,

nothing in *McMurry* teaches or suggests applying the conversion reaction to any specific chemical compound to get a specific analog that is relevant or similar to the compound of *Keller*. Specifically, nothing in *McMurry* teaches or suggests applying the conversion reaction to the chemical compound of *Keller* to arrive at the Applicant's claimed class of compounds. In fact, *McMurry* does not teach or suggest that the conversion reaction is applicable to compounds that have two different functional groups or those that have a maleimide functional group. As such, there is no rationale or suggestion in *Keller* and *McMurry* to combine the teachings of *Keller* with the teachings of *McMurry*.

Additionally, Applicant respectfully asserts that *McMurry*, by teaching the conversion reaction alone, does not provide a sufficient suggestion for being motivated with *Keller*. While *McMurry* does teach the conversion reaction, it does not teach or suggest that the conversion reaction is applicable to all molecules. In fact, *McMurry* states that the reaction is difficult and often requires heating in tetrahydrofuran solvent to go to completion. As such, there is no teaching or suggestion arising from *McMurry* that the conversion reaction is applicable to all molecules having a carboxylic acid, or is applicable to molecules having multiple functional groups. Thus, there is no logical connection between *Keller* and *McMurry* to provide sufficient motivation or suggestion that the conversion reaction of *McMurry* is applicable to molecules having multiple types of functional groups or molecules having a maleimide functional group.

Further, Applicant respectfully asserts that the mere fact that *Keller* and *McMurry* can be combined is not sufficient to establish a *prima facie* case of obviousness. It is well known that the mere fact that references can be combined is not sufficient to establish a *prima facie* case of obviousness. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). As such, just because the compound of *Keller* has a carboxylic acid functional group and *McMurry* teaches a conversion reaction to convert carboxylic acid functional groups to primary alcohols is not a reason alone to suggest the combination of references; especially in view of the maleimide functional group on the compound of *Keller*.

Since there is no suggestion or motivation arising from either reference to make the proposed combination of references, a *prima facie* case of obviousness has not been established. As such, Applicant respectfully requests withdrawal of the rejection.

3. No Reasonable Expectation of Success

Applicant respectfully asserts that there is no reasonable expectation of success in arriving at the claimed invention by *Keller* and *McMurry*, alone or in combination. Specifically, Applicant respectfully asserts that the maleimide functional group on the compound of *Keller* precludes any reasonable expectation of success that the conversion reaction of *McMurry* can convert the compound of *Keller* into a compound of the claimed invention. In part, this is because *Keller* affirmatively teaches the maleoyl group (*i.e.*, maleimide functional group) of the compound can be cleaved by mild alkaline and acid hydrolysis. In another part, this is because *McMurry* teaches the conversion reaction proceeds with a powerful hydride reagent, such as lithium aluminum hydride, to yield a primary alcohol, and the reaction is difficult and often requires heating in tetrahydrofuran solvent to go to completion.

Applicant respectfully asserts that if the maleoyl group is cleaved or otherwise altered by the conversion process of *McMurry*, a compound of the claimed invention will not be generated by the conversion reaction. As such, the conversion reaction of *McMurry* may cause the maleoyl group to be cleaved or otherwise altered as suggested by *Keller*. This is because only mild alkaline and acid hydrolysis can cause such cleavage and the conversion reaction of *McMurry* proceeds with a powerful hydride reagent. Accordingly, one of ordinary skill in the art may not have a reasonable expectation of success because it is not known from the teachings of *Keller* and *McMurry* whether or not the maleoyl group is cleaved or otherwise altered by the conversion reaction. Since both *Keller* and *McMurry* are devoid of discussing whether or not the maleoyl group would be cleaved or otherwise altered by a powerful hydride reagent, such as lithium aluminum hydride, and *Keller* affirmatively states that only mild alkaline and acid hydrolysis can cause such cleavage, there is no reasonable expectation of arriving at the claimed invention. Therefore, there is no reasonable expectation of success and Applicant respectfully requests withdrawal of the rejection.

B. Rejections Under 35 U.S.C. § 112: Written Description Requirement

The Examiner rejects claims 1-2, 5-6, 8-9, 11-12, 14-15, and 17-18 under 35 U.S.C. § 112 first paragraph, as failing to comply with the written description requirement. The Applicant respectfully traverses the rejection because the specification describes the claimed chemical compounds with sufficient clarity and in such a way as to reasonably convey to one skilled in the

art that the claimed invention was in the possession of the Applicant at the time of filing the application for patent. Examiner's rejection is based on the assertion that the specification does not teach how to make the claimed invention; however, Applicant claims compounds (which are shown in the specification) and not methods of making the compounds.

Applicant respectfully asserts that the application complies with the written description requirement. Also, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims"). Applicant contends that the chemical structures of the claims were adequately presented in the specification as filed. In part, this is because Applicant can show possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). This can include showing the invention was ready for patenting such as by the disclosure of drawings or structural chemical formulas that show the invention was complete. *See, Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68; 119 S.Ct. 304, 312, 48 USPQ2d 1641 1647 (1998). As such, the specification, including the figures and chemical structures, shows Applicant was in possession of the claimed invention at the time of filing the application. Moreover, the spectrographic data provided in the application show possession of the invention at the time of filing the application.

Additionally, the Examiner asserts that the specification does not comply with the written description requirement because the specific methods of making the class of compounds are not explicitly set forth. However, Applicant respectfully points to paragraph [0062], which states, "[m]ethods for forming the foregoing molecules are readily known to those skilled in the art. For example, see Example 9 hereinbelow." Also, "the law is clear that patent documents need not include subject matter that is known in the field of the invention and is in the prior art, for patents are written for persons experienced in the field of the invention. ... To hold otherwise would require every patent document to include a technical treatise for the unskilled reader." *S3 Inc. v. nVIDIA Corp.*, 259 F.3d 1364, 1371, 59 USPQ2d 1745, 1749-50 (Fed. Cir. 2001) citing *Vivid Technologies, Inc. v. American Science and Engineering, Inc.*, 200 F.3d 795, 804, 53

USPQ2d 1289, 1295 (Fed. Cir. 1999) ("patents are written by and for skilled artisans"). Accordingly, from the specification one of ordinary skill in the art would be capable of making the claimed class of compounds, and the details of well-known chemical reactions do not need to be explicitly recited. Additionally, Example 9 shows the simplicity of the synthesis of compounds which are similar in structure and function with the claimed compounds.

Applicant respectfully asserts that the methods of forming the compounds of the claimed invention are well within the skill of one of ordinary skill in the art. In part, this is because the claimed compounds are not so complex that new chemistry is needed. Also, the specification affirmatively states that methods for forming the foregoing molecules are readily known to those skilled in the art. Thus, by reviewing the chemical structures of the claimed invention, one of ordinary skill in the art would understand that the inventor had possession of the claimed invention. In fact, the court has already held that an Applicant can show possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means: as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See *Lockwood* at 1966. Applicant respectfully asserts that the claimed invention is drawn to compounds as illustrated in the specification and not to methods of making the invention.

Since the specification, including the figures and chemical structures that correlate with the spectrographic data, shows Applicant was in possession of the claimed invention at the time of filing the application, Applicant respectfully asserts that the written description requirement is fully satisfied. Thus, Applicant respectfully requests that the rejection be withdrawn.

C. Rejections Under 35 U.S.C. § 112: Enablement Requirement

The Examiner rejects claims 3, 4, 10, and 16 under 35 U.S.C. § 112 first paragraph, as failing to comply with the enablement requirement. The Applicant respectfully traverses the rejection because the Applicant has described the claimed chemical compounds with sufficient clarity and in such a way as to enable one skilled in the art to which it pertains to make and/or use the claimed chemical compounds at the time of filing the application for patent.

Applicant respectfully asserts that one skilled in the art to which it pertains would be able to make and/or use the claimed chemical compounds at the time of filing the application for patent. In part, this is because the chemical structures of the claimed compounds are shown and

are not so complex that new chemistry is needed to synthesize the compounds. It is well known that a patent must contain a description that enables one skilled in the art to make and use the claimed invention. *Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). "An inventor need not, however, explain every detail since he is speaking to those skilled in the art." *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981). "Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be." *In re Gay*, 309 F.2d 769, 774, 135 USPQ 311, 316 (CCPA 1962). "That some experimentation is necessary does not preclude enablement; the amount of experimentation, however, must not be unduly extensive." *Atlas Powder*, 750 F.2d at 1576, 224 USPQ at 413. *See also W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed. Cir.), *cert. denied*, 105 S. Ct. 172 (1984); *In re Angstadt*, 537 F.2d 498, 503, 190 USPQ 214, 218 (CCPA 1976). The specification provides teachings such that one of ordinary skill in the art would be capable of making and using the claimed class of compounds, and the details of well-known chemical reactions do not need to be explicitly recited. Specifically, paragraph [0062] provides enablement for making the claimed class of chemical compounds, which are adequately depicted and described within the specification. Thus, the enablement requirement has been satisfied.

The Examiner alleges that "the 'how to make' requires a disclosure not only of the reaction conditions required to produce all the embodiments of the invention as claimed generically but also how to obtain the starting materials employed to do so, without undue experimentation or the exercise of inventive skill to do so." Applicant respectfully asserts that it would not require undue experimentation or the exercise of inventive skill to practice the claimed invention because the chemical structures are simple and depicted in the specification. As such, a skilled artisan would be able to review the chemical structure in order to determine the starting materials and reactions for producing the chemical structures without undue experimentation. In fact, paragraph [0062] of the specification affirmatively states that methods for forming the foregoing molecules are readily known to those skilled in the art.

Since the specification, including the figures and chemical structures that correlate with the spectrographic data, shows one of ordinary skill in the art to which the claimed invention pertains how to make and/or use the claimed chemical compounds at the time at the time of

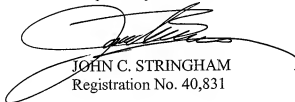
filing the application, Applicant respectfully asserts that the enablement requirement is fully satisfied. Thus, Applicant respectfully requests the rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicant believes the claims as amended are in allowable form. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 9 day of August 2006.

Respectfully submitted,



JOHN C. STRINGHAM
Registration No. 40,831

JONATHAN M. BENNS
Registration No. 53,983
Attorneys for Applicant
(801) 533-9800

JCS:JMB:mla

MLA0000005209V001.DOC